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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,975	12/17/2001	Christiane Yoakim	13/073	6581

28513 7590 03/07/2003

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EXAMINER

SAEED, KAMAL A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/07/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,975

Applicant(s)

YOAKIM ET AL.

Examiner

Kamal A Saeed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) 1 is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-53 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, are drawn to compounds of **Formula I**, as defined in claim 1, and their pharmaceutical composition, variously classified in classes 514, 544, 546, 548, 549 and several subclasses.
- II. Claims 40-42, are drawn to a method of use of compounds of **Formula I**, as defined in claim 1, variously classified in class 514, 544, 546, 548, 549 and several subclasses.
- III. Claim 43, is drawn to intermediate compound of **Formula vi**, as defined in claim 43, classified in class 548 and several subclasses.
- IV. Claim 44, is drawn to intermediate compound of **Formula xx**, as defined in claim 44, classified in class 548 and several subclasses.
- V. Claim 45 and 46, are drawn to intermediate compounds of **Formula xxvi** and **xxxii**, as defined in claim 45, classified in class 548 and several subclasses.
- VI. Claims 47-51, are drawn to a process of preparing compounds of **Formula I**, as defined in claim 47, by hydrolyzing intermediate compound of **Formula vi** , classified in class 548, 549, and several subclasses.

- VII. Claims 47-51, are drawn to a process of preparing compounds of **Formula I**, as defined in claim 47, by hydrolyzing intermediate compound of **Formula xx**, classified in class 548, 549, and several subclasses.
- VIII. Claims 52-54, are drawn to a process of preparing compounds of **Formula I**, as defined in claim 52, by hydrolyzing intermediate compound of **Formula xxiv**, classified in class 548, 549, and several subclasses.

The inventions are distinct, each from the other because of the following reasons:

Invention Groups I and Groups III, IV or VI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as antiviral agents and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Invention Groups I and Groups VI, VII or VIII are related as product and process of making thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make another materially different product or (2) that the product as claimed can be made by another materially different process (MPEP

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806.05(f)). In the instant case, the product as claimed can be made by another materially different process as is clearly evident from claims 47-54. Therefore a separate search considerations are involved, which would impose a burden if unrestricted.

Inventions Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of using the product can be practiced by another materially different product as shown in examples, in pages 57-81. Therefore a separate search considerations are involved, which would impose a burden if unrestricted.

Accordingly, along with the election of one of the above groups, the following action is also taken.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising, for example, the compositions of compounds of (1) Example 1085, page 33; Example 1028, page 59 etc. (2) a method of inhibiting the replication of papillomavirus using the compounds using compounds of Example 1085, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purpose as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Upon the election of a single disclosed species (e.g. Example, page number and structural depiction), a generic concept, inclusive of the elected species, will be identified by the Examiner for examination. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

In accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims, process of making and method of use is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised the process of use are amended during prosecution to maintain either dependency on the product claims or to otherwise include limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

A telephone call was made to Philip I. Datlow, on 02/20/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

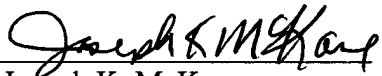
Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

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published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG
89.

Any inquiry of a general nature or relating to the status of this application should be
directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed, Ph.D
March 3, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1